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09/19/2005

Dario Neri

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EXAMINER

LIU, SUE XU

ART UNIT

PAPER NUMBER

1639

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,140	<b>Applicant(s)</b> NERI ET AL.	
	<b>Examiner</b> SUE LIU	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8,10,12,18,23,30 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,12,18,23,30 and 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6 and 7 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                 |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application       |
| Paper No(s)/Mail Date <u>10/3/06; 1/24/08</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

## **DETAILED ACTION**

### ***Claim Status***

1. Claims 2, 5, 9, 11, 13-17, 19-22, 24-29 and 31-33 have been cancelled. (It is presumed that claim 32 is cancelled).

Claim 40 has been added.

Claims 1, 3, 4, 6-8, 10, 12, 18, 23, 30 and 34-40 are currently pending.

Claims 8, 10, 12, 18, 23, 30 and 34-40 have been withdrawn.

Claims 1, 3, 4, 6 and 7 are being examined in this application.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group 1 (claims 1-7) in the reply filed on 1/24/08 is acknowledged. The traversal is on the ground(s) that there is unity of invention. This is not found persuasive because the unity of invention is lacking. Applicants traversed the lack of unity by asserting the previously cited references (Winkler and Burmer) do not teach the special technical feature of the instant claims. In response, the instant claims lack unity of invention because each group of the invention has a different technical feature. For example, the technical feature for Group 1 invention is a chemical compound comprising a chemical moiety and an oligonucleotide; the technical feature for Group 2 invention is a chemical library; the technical feature for Group 3 invention is a method of screening and/or biopanning. Therefore, Groups 1-3 are not so linked by the same or a corresponding special technical feature as to form a single inventive concept. In addition, the special technical feature of Group 1 is known in the prior art.

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Applicants are respectfully directed to the rejection under 35 USC 102(b) for discussion of how the cited Harbury and Distefano references teach all elements of the claimed invention.

Applicants argue the Winkler reference is different from the technical feature recited in the instant claim 1, because Winkler teaches the tag “comprise amplification and differential domains”, which is different from the “self assembly moiety”. However, applicants do not point out the specific structural difference between the said elements. Regardless what the Winkler reference names its nucleic acid domains, the regions of the nucleic acid molecules are structurally the same as the instant claimed nucleic acid molecules. It is noted that the instant specification does not specifically define the term “self assembly moiety” to be of any particular structure (such as a particular sequence). Applicants have not demonstrated the nucleic acid molecule of the Winkler reference is structurally different from the technical feature of “an oligonucleotide” linked to a “chemical moiety.”

Applicants traversed the Burner reference with similar argument as the traversal over the Winkler reference by arguing the Burner reference does not explicitly teach “the “self-assembly domain”. As discussed above, the term “self-assembly moiety/domain” is not specifically defined as any particular structure. All nucleic acid sequences can hybridize (or self-assemble) with its complementary sequence (as evidenced by applicant’s own disclosure). In addition, a demonstration of lack of unity does not require that the prior art teach all elements of the instant claims, rather it requires the “technical feature” is known in the prior art. As discussed above and previously, the technical feature of the Group 1 invention is an oligonucleotide with a chemical moiety (which the term “chemical moiety” is also broad and can encompass any chemicals including an atom or a chemical compound such as a nucleotide residue). The Burner reference

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teaches an oligonucleotide with a chemical moiety. Thus, the technical feature has been demonstrated to be known in the prior art and unity is lacking.

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

3. This application is filed under 35 U.S.C 371 of PCT/EP02/04153 (filed on 04/15/2002), which claims priority to US provisional applications 60/362,599 (filed on 03/08/2002).

### ***Information Disclosure Statement***

4. The IDS filed on 10/3/06 and 1/24/08 have been considered. See the attached PTO 1449 forms. Please also note the crossed out citations indicating no copies were provided for the crossed out citations.

### ***Specification***

#### **Sequence Rule Compliance**

5. "In order to expedite the processing of applications, minor errors pertaining to compliance with the sequence rules may be handled with the first Office action." See MPEP 2427.01.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2).

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However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) below:

Please refer to the attached “Notice to Comply” form.

In order to be fully responsive to the instant office action, applicants must comply with the Sequence Rule as indicated in the Notice to Comply form.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.

### ***Claim Objections***

7. Claim 4 is objected to because of the following informalities: The phrase “oligonucleotideor” appears to be a typographic error of. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### ***Written Description Rejection***

9. Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a combination reaction produce comprising various elements.

*To satisfy the written description requirement, applicants may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.*

*Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.*

*The written description requirement of 35 U.S.C. 112 exists independently of enablement requirement, and the requirement applies whether or not the case involves questions of priority. The requirement applies to all inventions and includes chemical inventions. The fact that the patent is directed to method entailing use of compounds, rather than to compounds per se, does not remove patentee's obligation to provide a description of the compound sufficient to distinguish infringing methods from non-infringing methods. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004).*

*With regard to the description requirement, applicants' attention is invited to consider the decision of the Court of Appeals for the Federal Circuit, which holds that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].*

*The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species or by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d at 1568, 43 USPQ2d at 1406.*

The instant claim 1 is broadly drawn to a genus of combination reaction products having various elements. Claim 1 is also drawn to a genus of chemical moiety, which can be any chemical entity/compounds; claim 1 is also drawn to a genus of oligonucleotides as well as

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“functional analogue”. Neither the instant specification nor the claims have demonstrated common structure and/or function for the claimed genus chemical moiety (that can be attached to oligonucleotide or its functional analogue), the genus of oligonucleotide, and the genus of “functional analogue”. In addition, no representative numbers of species for each claimed genus is provided to show possession of the claimed genres.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. (see MPEP 2163 II).

In this case, the instant application only prophetically described making oligomers having a chemical moiety attached and forming duplex structures. The only example provided is oligonucleotides with attached thiol group. The instant disclosure does not describe that any chemical entities can be linked with oligonucleotides and subsequently form duplex structures. In addition, the instant specification does not provide any examples of “functional analogues” of oligonucleotides that can be linked to chemical moieties and used for duplex formation through self-assembly.

Therefore, applicants are not in possession of the entire claimed genus of any chemical moiety, any oligonucleotide, or any functional analogue thereof. Applicant’s claimed scope represents only an invitation to experiment regarding possible chemicals/oligonucleotides/functional analogues that might be used for the purpose of producing “combination reaction products”.



***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Harbury**

11. Claims 1, 3, 4, 6 and 7 are rejected under **35 U.S.C. 102(b)** as being anticipated by **Harbury** et al (WO 200023458; 4/27/2000; cited in IDS).

The instant claims recite a combination reaction produce comprising various elements.

Harbury et al, throughout the publication, teach oligonucleotide tag having a chemical compound (e.g. Abstract; Claims; Figures).

For **claim 1**: “*a chemical moiety*”: The reference teaches linking a chemical compound (such as a chemical reaction site) to a nucleic acid tag (e.g. claims; Figure 1), which the chemical reaction site (i.e. chemical compound) or any of the nucleic acid residue (such as the end residue) read on the “chemical moiety” as the term is broadly and reasonably interpreted (to be of any “chemical moiety”).

“*an oligonucleotide...*”: The reference teaches various nucleic acid tags having different hybridization sequences (e.g. Abstract; Claims; Figures), which a portion of the nucleic acid sequence reads on the “self-assembly moiety” and another portion reads on the “coding

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sequence” as the said terms can be broadly and reasonably interpreted. The reference also teaches the nucleic acid tags are “unique” to the linked chemical structures (e.g. p.10, ll 6+).

*“at least two chemical compounds are bound to each other...”*: The reference also teaches hybridizing the nucleic acid tags together to direct chemical synthesis (e.g. p.4, line 15; pp.10-11; claims; Figures).

For **claim 3**: The recitation of “is capable of covalently linking...” is a recitation of intended use or inherent property of the claimed product. Generally, a recitation of intended use is not afforded patentable weight as the intended use language does not provide additional structural limitation. It is also an inherent property of the nucleic acid molecules to be able to form covalent linkage. For examples, Harbury reference teaches compounds are “covalently” attached to the nucleic acids (e.g. p.3, lines 35); **Pospisilova** et al., (Photochemistry and Photobiology. Vol.64(4): 386-390; 1998), teaches nucleic acids duplexes can be cross-linked by under the appropriate condition, which cross-linking forms covalent bonds among the hybridized nucleic acid molecules (e.g. Abstract; p.388, right col.).

For **claim 4**: The reference teaches compounds are “covalently” attached to the nucleic acids (e.g. p.3, lines 35), and each nucleic acid residues are also covalently linked together.

For **claim 6**: The reference teaches various identifier sequences in the nucleic acid tags that are located between hybridization and the attached chemical compound (e.g. Figure 1; p.12).

For **claim 7**: The reference teaches forming hybridization product (duplex or dimer) (e.g. Figures; Claims).

Distefano

12. Claims 1, 3, 4, 6 and 7 are rejected under **35 U.S.C. 102(b)** as being anticipated by **Distefano** et al (PNAS. Vol.90: 1179-1183; 1993; cited in IDS).

Distefano et al, throughout the publication, teach oligonucleotide tag having a chemical moiety (e.g. Abstract; Figure 1).

For **claim 1**: “*a chemical moiety*”: The term “chemical moiety” is not specifically defined to be of any particular structure. Given the broadest and reasonable interpretation, the said term “chemical moiety” can be any chemical entity/compound. For example, the term “chemical moiety” broadly encompasses nucleic acid residues, the various chemical groups of nucleic acid residues, etc. The reference teaches oligonucleotide with various nucleotide residues (e.g. Figure 1), which any of the nucleic acid residue (such as the end residue) reads on a chemical moiety.

“*an oligonucleotide...*”: The reference teaches various nucleic acid molecules such as the ones show in Figure 1 (e.g. Abstract; Claims; Figures), which a portion of the nucleic acid sequence reads on the “self-assembly moiety” and another portion reads on the “coding sequence” as the said terms can be broadly and reasonably interpreted. The reference also teaches the nucleic acid tags are “unique” to the linked chemical structures because each of the hybridized nucleic acid molecules has at least one unique sequence (as shown in Figure 1).

“*at least two chemical compounds are bound to each other...*”: The reference also teaches hybridizing the nucleic acid molecules together to form a dimer and/or trimer (e.g. Figures; pp.1180+).

For **claim 3**: The recitation of “is capable of covalently linking...” is a recitation of intended use or inherent property of the claimed product. Generally, a recitation of intended use

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is not afforded patentable weight as the intended use language does not provide additional structural limitation. It is also an inherent property of the nucleic acid molecules to be able to form covalent linkage. For example, Pospisilova et al., (Photochemistry and Photobiology. Vol.64(4): 386-390; 1998), teaches nucleic acids duplexes can be cross-linked by under the appropriate condition, which cross-linking forms covalent bonds among the hybridized nucleic acid molecules (e.g. Abstract; p.388, right col.).

For **claim 4**: The reference teaches all the nucleic acids residues are “covalently” attached to each other to form the polymer (e.g. pp.1179+).

For **claim 6**: Any of the unique sequences between the two ends of the oligonucleotides read on the coding sequence (e.g. Figure 1).

For **claim 7**: The reference teaches forming hybridization product (duplex or trimer) (e.g. Figures).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/  
Primary Examiner, AU 1639  
6/26/09